ArthroCare®

510(k) Summary
ArthroCare® Corporation
ArthroCare® Coblator IQ™ Perc-D® SpineWands®

General Information

Submitter Name/Address:	ArthroCare Corporation 7000 West William Cannon Dr. Austin, TX 78735
Establishment Registration Number:	3006524618
Contact Person:	Shirley Hyink Sr. Manager, Regulatory Affairs
Date Prepared:	July 2, 2013

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Device Description

Trade Name:	ArthroCare® Coblator IQ™ Perc-D® SpineWand® (Coblator IQ DLR and DLG SpineWands)
Generic/Common Name:	Electrosurgical Device and Accessories
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)

Predicate Devices

K100353 - ArthroCare Coblator IQ Perc-D SpineWand (May 13, 2010)

Product Description

The Coblator IQ Perc-D SpineWands consist of two Wands, the Coblator IQ DLR SpineWand and the Coblator IQ DLG SpineWand, intended for use only with the Coblator IQ Controller.

These wands are single use, disposable, high frequency electrosurgery devices intended for use in percutaneous spinal disc decompression surgery. The Wands consist of a stainless steel shaft with a straight electrode configuration design. The proximal end of the devices is housed in a handle composed of polycarbonate. A cable integrated into the handle connects the Wand to the ArthroCare Coblator IQ Controller.

The Wand electrode is activated using the CIQ Controller System energy which starts the Coblation process to ablate the disc tissue. The Coblation process involves use of a conductive media to create a plasma layer to ablate tissue.

Intended Use/Indications For Use

The ArthroCare Coblator IQ Perc-D Spine Wands (Coblator IQ DLR and Coblator IQ DLG SpineWands) are indicated for ablation, coagulation, and decompression of disc material to treat symptomatic patients with contained herniated lumbar and lumbosacral discs. The Wands are designed to be used exclusively with the ArthroCare Coblator IQ Controller.

Non-Clinical Data

This submission seeks only to clarify the indication for use statement of the predicate device and there have been no other device, design or material changes since the previous clearance of these predicate devices (K100353), new testing was deemed to be unnecessary. The performance testing previously conducted as part of the design control activities include device acceptance criteria testing, biological testing, and packaging testing.

Clinical Data

No clinical data are included in this submission.

Summary

The purpose of this submission is to clarify the current indication for use statement to specifically denote use of the Wands within the lumbar and lumbosacral spine. Other than the change to the indication of use statement the Wands are identical to the predicate devices in:

- Performance specification,
- Materials,
- Technological characteristics,
- Sterilization, and
- Principle of operation

The proposed Indications for Use do not significantly affect the safety or efficacy of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 22, 2013

Shirley Hyink
Senior Manager, Regulatory Affairs
ArthroCare Corporation
7000 West William Cannon Drive
Austin, Texas 78735

Re: K132099
Trade/Device Name: ArthroCare® Coblator IQ™ Perc-D® SpineWand®
(Coblator IQ DLR and DLG SpineWands)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 3, 2013
Received: July 10, 2013

Dear Ms. Hyink:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132099

Device Name: ArthroCare® Coblator IQ™ Perc-D® SpineWand® (Coblator IQ DLR and DLG SpineWands)

Indications for Use:

The ArthroCare Coblator IQ Perc-D Spine Wands (Coblator IQ DLR and Coblator IQ DLG SpineWands) are indicated for ablation, coagulation, and decompression of disc material to treat symptomatic patients with contained herniated lumbar and lumbosacral discs. The Wands are designed to be used exclusively with the ArthroCare Coblator IQ Controller.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S

(Division Sign-off)
Division of Surgical Devices
510(k) Number K132099